K002429

Premarket Notification
Nucletronn SelectSeed I-125
Date : 18 July, 2000

FEB - 2 2001

Nucletron

NUCLETRON B.V.
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Department of Health and Human Services
Center of Device and Radiological Health
Office of Device Evaluation
Pre-Market Notification Section

510(K) SUMMARY OF SAFETY AND EFFECTIVENESS INFORMATION

as required by section 807.92(c)

a. Submitter of 510(k)

Company name:	Nucletron Corporation
Registration #	1121753
Address:	7080 Columbia Gateway Drive Columbia, MD 21046-2133
Contact Person:	Robert Applebaum, C.H.P., R.S.O. Director Assurance & Regulatory Affairs
Phone:.	410-312-4100
Fax:	410-312-4197

b. Device Name:

Trade/Proprietary Name:	SelectSeed I-125
Common/Usual Name:	Iodine-125 Source for Interstitial Brachytherapy
Classification Name:	Radionuclide brachytherapy source 21 CFR 892.5730, Class II.

c. Legally Marketed Predicate Device(s)

Our device is substantially equivalent to the legally marketed predicate device cited in the table below:

The following devices listed below represent the predicate devices used for substantial equivalence. These devices are currently marketed products with current premarket notification numbers.

Device	Premarket #
Uromed Brachytherapy Iodine-125 Sources	K982226
Amersham Healthcare I-125 Seeds Model 6711	K914281
North American Scientific Seed, Io Gold	K964647

d. Description

The **SelectSeeds I-125** are cylindrical sealed sources containing I-125 radioactivity. The sources are 4.5 mm long and 0.8 mm in diameter. The outer capsule of the source is composed of titanium being closed at one end and sealed by a laser weld at the other end in a final step. The iodine I-125 is deposited as silver iodine (AgI) on a silver bar. The silver bar also serves as an x-ray marker.
Iodine seeds have a half live of 59.46 days and are available in a range of activity levels. The Select Seeds I-125 are provided sterile in a magazine.

12.4. Specifications
The **SelectSeed I-125** dimensions are as follows: the length is 4.5 mm; the diameter is 0.8 mm; the wall thickness is 0.05 mm and the isotope is iodine-125.

12.5 Materials

Component	Patient Contact	Material	Current use in Marketed Products
Outer capsule	yes	Titanium	Outer capsules for radioactive seeds: UroMed Iodine-125 Brachytherapy source, Amersham Healthcare I-125 source, North American Scientific source
Iodine carrier	no	Iodine deposited on silver bar	Amersham Healthcare I-125 source
X-ray marker	no	Silver	Amersham Healthcare I-125 source
Iodine-125	no	Iodine-125 compound	UroMed Iodine-125 Brachytherapy source, Amersham Healthcare I-125 source, North American Scientific source

The materials used in the construction of the **SelectSeed I-125** are widely used in the medical device industry and generally regarded as safe for use by health care professionals.
Quality Controls
Select Seeds I-125 will be manufactured in accordance with a strict quality assurance program and in compliance with the standards listed in section 1.11.
Sources will be integrity and leak tested in accordance to ANSI 43.6 Annex A / ISO 9978 These tests will include a leak test by immersion.
Each source will be checked individually. The measurements will be NIST-traceable to ensure that radiation is within the limits specified. The manufacturer will provide NIST with a sample source for calibration as well.
Details on Structure, Type, Intensity and Distribution of Radiation

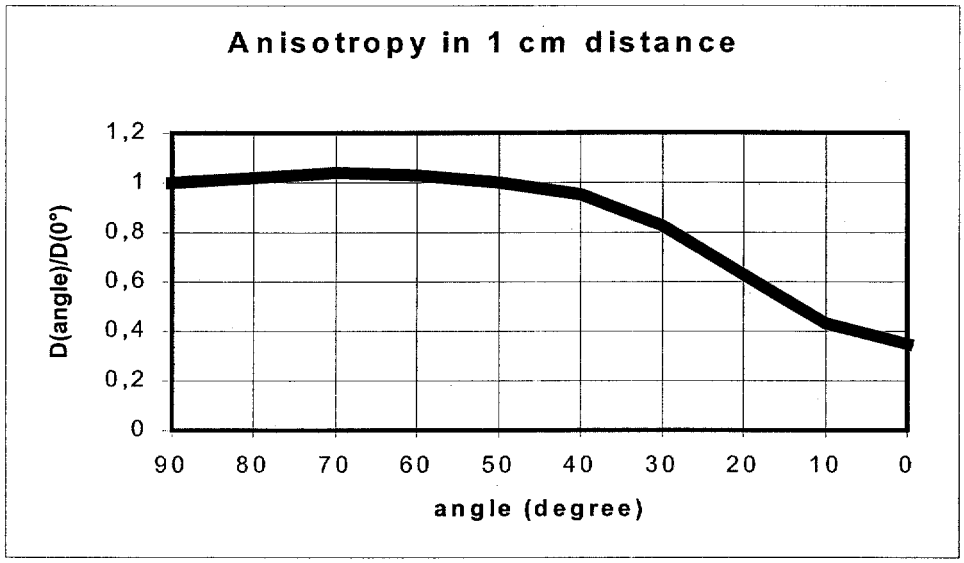
The dose distribution around the seed has been specified in accordance with the AAPM TG 43 protocol. In order to validate the values Monte-Carlo-calculations and measurements were carried out.
The AAPM TG 43 formalism is designed to calculate the dose at any point in water around the seed according

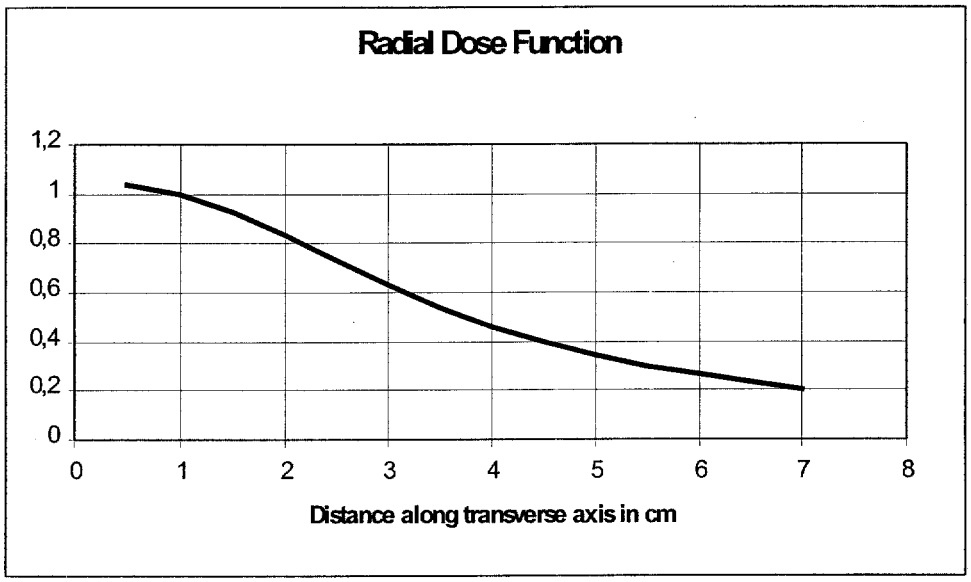
$$\dot{D}(r,\theta) = S_K \cdot \Lambda \cdot \frac{G(r,\theta)}{G(r_0,\theta_0)} \cdot F(r,\theta) \cdot g(r)$$

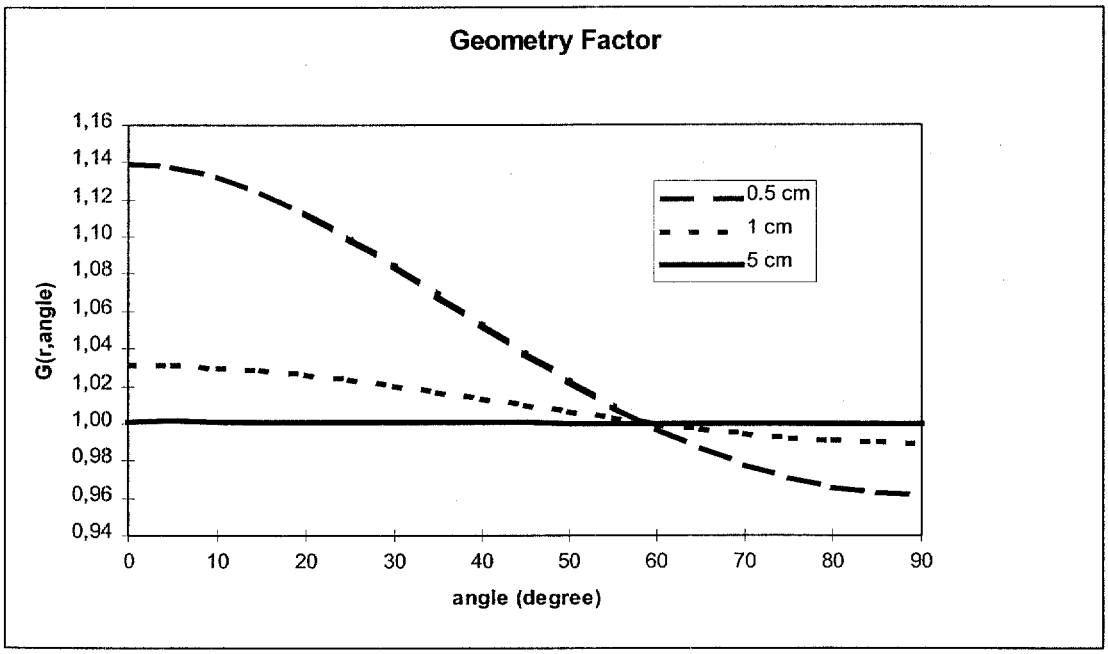
where

S_K	measured air kerma strength
Λ	dose rate constant
$G(r,\theta)$	geometry function
$F(r,\theta)$	anisotropy function
$g(r)$	radial dose function
(r_0,θ_0)	reference point, assumed on the transversal bisector ($r_o = 1cm$, $\theta_0 = \pi / 2$

The air kerma strength is traceable to a calibration done by NIST and is characteristic for the source. The recommended dose rate constant is 0.88 cGy hr-1 U-1. The geometry function , the radial dose function and the anisotropy function for a distance from 1 cm are shown in figure 1 to 3. From the radial dose function it is possible to calculate the dose depth distribution.




Radial Dose Function
1,2
1
0,8
0,6
0,4
0,2
0
0
1
2
3
4
5
6
7
8
Distance along transverse axis in cm


Geometry Factor
1,16
1,14
1,12
1,10
1,08
1,06
1,04
1,02
1,00
0,98
0,96
0,94
G(r,angle)
0.5 cm
1 cm
5 cm
0
10
20
30
40
50
60
70
80
90
angle (degree)

e. Intended use

APPLICATION INDICATIONS

Indications

The **SelectSeeds I-125** are used for interstitial seed implantation therapy of localized tumours, especially in the prostate.

Contraindications

Treatment of tumours in a generally bad or ulcerated state is not recommended.

Adverse reactions

Since the therapeutic effect is achieved by radioactive radiation, radiation damage can occur in healthy tissue.

Possible adverse reactions associated with implant usage in the prostate have been reported to include irritative uropathy symptoms including increased urinary frequency, urgency and obstruction. Complications have also included cystitis, urethritis, superficial urethral necrosis, hematuria, stricture and contracture, impotence, incontinence and proctitis.

Implantation

The **SelectSeeds I-125** are implanted using the seed loading device **Seed Selectron** only. Special hollow needles are inserted into the cancerous tissue with the aid of an applicator (template). The needles are connected once per once with the Seed Selectron, which will insert the seeds automatically in the needle and will retract the needles according the length of the seed/spacers train. The needles are inserted before the connection with the Seed Selectron according of the current technique for treating prostate carcinoma. The insertion of the needles is a transperineal implantation procedure. Further information can be found in the literature listed in Chapter 15.

Implantation of the SelectSeeds I-125 must be carried out by appropriately qualified medical experts.

Accessories

The implantation of the **Select Seeds I-125** has to be carried out using appropriate medical instrumentation such as **Seed Selectron**, **Implantation needles, Spacers** and other sterile and disposable accessories delivered **only** by **Nucletron.**

f. Summary of technological considerations

The Nucletron SelectSeed I-125 is substantially equivalent to the predicate device. It combines the functionality, components and design of the predicate device while incorporating a new material.

D. Kindlein — 18. July 2000

Name: Johann Kindlein
Title Product Manager
Nucletron BV
Veenendaal
Netherlands

Date

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB - 2 2001

Mr. Robert Applebaum
Regulatory Affairs Manager
Nucletron Corporation
7080 Columbia Gateway Drive
COLUMBIA MD 21046-2133

Re: K002429
Nucletron SelectSeed 1-125
Dated: November 28, 2000
Received: November 29, 2000
Regulatory class: II
21 CFR 892.5730/Procode: 90 KYK

Dear Mr. Applebaum:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4639. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Daniel G. Schultz, M.D.
Captain, USPHS
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure (s)

Premarket Notification
Nucletronn SelectSeed I-125
Date : 18 July, 2000

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Statement of intended use

Device Name: **Nucletron SelectSeed I-125**

Intended use

Indications

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Prescription use

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J. Kindlein — 18. July. 2000

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David C. Seymour
(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K002429